



**[Billing Code 4140-01-P]**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Request for Information (RFI): Input into the Deliberations of the Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research**

**SUMMARY:** The National Institutes of Health Council of Councils has established a working group to provide recommendations to the Council on: (1) implementing the guiding principles and criteria contained within the Institute of Medicine report, “Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity”, and (2) the size and placement of the research active and inactive populations of NIH-owned or -supported chimpanzees. See [http://dpcpsi.nih.gov/council/working\\_group.aspx](http://dpcpsi.nih.gov/council/working_group.aspx) for the working group’s charge and roster. The NIH is seeking public input to inform the working group’s deliberations.

**BACKGROUND:** The use of animals in research has enabled scientists to identify new ways to treat illness, extend life, and improve health and well-being. Chimpanzees are our closest relatives in the animal kingdom, providing exceptional insights into human biology and the need for special consideration and respect. While used very selectively and in limited numbers for medical research, chimpanzees have served an important role in advancing human health in the past. However, new methods and technologies

developed by the biomedical community have provided alternatives to the use of chimpanzees in several areas of research.

In December 2010, the National Institutes of Health commissioned a study by the Institute of Medicine (IOM) to assess whether chimpanzees are or will be necessary for biomedical and behavioral research. The IOM issued its findings on December 15, 2011, with a primary recommendation that the use of chimpanzees in research be guided by a set of principles and criteria. The committee proposed three principles which must all be applied to analyze current and potential future research using chimpanzees.

1. That the knowledge gained must be necessary to advance the public's health;
2. There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects; and
3. The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments (i.e., as would occur in their natural environment) or in natural habitats.

Based on its deliberations, the IOM committee concluded that “while the chimpanzee has been a valuable animal model in past research, most current use of chimpanzees for biomedical research is unnecessary.” The committee also concluded, however, that the following areas may continue to require the use of chimpanzees: a limited number of ongoing studies on monoclonal antibody therapies, research on comparative genomics, and non-invasive studies of social and behavioral factors that affect the development, prevention, or treatment of disease. The committee was unable to reach consensus on the necessity of the chimpanzee for the development of prophylactic hepatitis C virus

vaccine. While the committee encouraged NIH to continue development of non-chimpanzee models and technologies, it acknowledged that new, emerging, or re-emerging diseases may present challenges that may require the use of chimpanzees.

The Working Group is gathering input from various sources, including researchers, academic institutions, foundations, scientific societies, government and regulatory agencies, industry, and the public, to help inform the development of its recommendations to the Council of Councils on actions the NIH can take to implement the IOM recommendations and to consider the size and placement of the active and inactive populations of NIH-owned or -supported chimpanzees. The following are areas of their charge and examples of questions within each which might need to be considered when developing recommendations.

- Developing a plan for implementation of the IOM's guiding principles and criteria
- Factors to consider in reviewing currently active NIH-supported research using chimpanzees to advise on which studies currently meet the principles and criteria defined by the IOM report and advising on the process for closing studies if any do not comply with the IOM recommendations. For example: Criteria to assess "minimally invasive" procedures for comparative genomics and behavioral research and "ethologically appropriate" physical and social environments; Criteria to balance phasing out of the existing research without causing "unacceptable losses to research programs" or an unacceptable "impact on the animals".

- Factors to consider when advising on the size and placement of active and inactive populations of NIH-owned or-supported chimpanzees as a result of implementing the IOM recommendations. For example: Ways to address capacity issues that would accompany an increase in ‘inactive’ animals; Factors to consider in transitioning the animals that are newly inactive; How many and what would be the characteristics of animals held in reserve for future research, if any; The number of animals needed to maintain a viable number of research naïve animals but also genetic and social stability and sufficient diversity for unanticipated research needs.
- A review process for considering whether potential future use of the chimpanzee in NIH-supported research is scientifically necessary and consistent with the IOM principles. For example: Factors to consider in determining whether other models (e.g., in vitro, other in vivo) would be a “suitable model” for answering the research question; Research areas where alternative model development is recommended; Whether NIH should have a plan to maintain a minimal population of federally-owned chimpanzees and input on the design of the plan; Circumstances under which chimpanzees should be considered as a model for “a new, emerging, or reemerging disease or disorder that may present challenges to treatment, prevention, and/or control that defy non-chimpanzee models and available technologies”; Characteristics of the oversight committee responsible for reviewing future research proposals and determining whether they are consistent with the IOM criteria and whether they can be conducted.

**INFORMATION REQUESTED:** To ensure a thorough and comprehensive evaluation of the issues underlying the implementation of the IOM Report's guiding principles and criteria and the size and placement of NIH-owned or -supported animals, input is being sought from the biomedical research community, including:

- Foundations
- Scientific societies
- Government and regulatory agencies
- Industry
- NIH grantee institutions, and
- The public

Input is sought for each of the areas identified above. For any of the areas identified above and any other specific areas you believe are worthy of consideration by the working group, please identify the critical issues(s) and impact(s) on institutions, scientists, and the mission of NIH to perform research to improve human health.

Response to this RFI is voluntary. Responders are free to address any or all of the above items. Please note that the Government will not pay for response preparation or for the use of any information contained in the response. The NIH may make all responses available, including name of the responder. In addition, NIH will prepare and make available a summary of all input received which is responsive to this RFI.

**HOW TO SUBMIT A RESPONSE:** All comments must be submitted electronically to [http://grants.nih.gov/grants/guide/rfi\\_files/nih\\_chimp/add.cfm](http://grants.nih.gov/grants/guide/rfi_files/nih_chimp/add.cfm). Comments must pertain to the category for which feedback is requested and must conform to the word limit indicated. Responses to this RFI will be accepted through April 10, 2012. You will see an electronic confirmation acknowledging receipt of your response, but will not receive individualized feedback on any suggestions. No basis for claims against the U.S. Government shall arise as a result of a response to this request for information or from the Government's use of such information.

**FOR FURTHER INFORMATION CONTACT:** Specific questions about this RFI should be directed to the following email address: [dpcpsi@od.nih.gov](mailto:dpcpsi@od.nih.gov).

Dated: February 13, 2012

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